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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,071	10/29/2003	Cynthia B. Robinson	02486.0071.NPUS01	9181

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WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
CAPPS, KEVIN J	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,071	ROBINSON ET AL.	
	Examiner	Art Unit	
	Kevin Capps	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 9-17 (in part), and 5, drawn to a composition comprising a non-glucocorticoid steroid and a tyrosine kinase inhibitor, classified in class 514, subclass 171.

II. Claims 1-4 and 9-17 (in part), and 6, drawn to a composition comprising a non-glucocorticoid steroid and a delta opioid receptor antagonist, classified in class 514, subclass 171.

III. Claims 1-4 and 9-17 (in part), and 7, drawn to a composition comprising a non-glucocorticoid steroid and a neurokinin receptor antagonist, classified in class 514, subclass 171.

IV. Claims 1-4 and 9-17 (in part), and 8, drawn to a composition comprising a non-glucocorticoid steroid and a VCAM inhibitor, classified in class 514, subclass 171.

V. Claims 18-21 (in part), drawn to a method of treatment comprising administering a composition comprising a non-glucocorticoid steroid and a tyrosine kinase inhibitor, classified in class 514, subclass 171.

VI. Claims 18-21 (in part), drawn to a method of treatment comprising administering a composition comprising a non-glucocorticoid steroid and a delta opioid receptor antagonist, classified in class 514, subclass 171.

VII. Claims 18-21 (in part), drawn to a method of treatment comprising administering a composition comprising a non-glucocorticoid steroid and a neurokinin receptor antagonist, classified in class 514, subclass 171.

VIII. Claims 18-21 (in part), drawn to a method of treatment comprising administering a composition comprising a non-glucocorticoid steroid and a VCAM inhibitor, classified in class 514, subclass 171.

Note: The Groups are classified based solely on the fact that the compositions of the instant inventions comprise a non-glucocorticoid steroid and a second agent. The different groups of secondary agents include many different classifications because many different chemical structures are encompassed by the broad functional classifications of the secondary agents.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operations. The different Groups are different compositions of matter that comprise distinct secondary agents in conjunction with the non-glucocorticoid steroids. The different secondary agents have different pharmacological functions and biological activities, and the chemical compounds encompassed by the secondary agent classifications have very different

atomic structures and chemical and physical properties. Thus, the different compositions have different designs and modes of operation.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. Because the general classes of secondary agents have acquired separate statuses in the art, and because they are different chemical compounds with different properties, different searches are required for each of the Groups, which presents a substantial burden to the Office.

4. Inventions V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are methods of treatment which comprise administering the distinct products discussed above. Because different compositions comprising distinct classes of agents are administered in the methods, the methods have different designs and modes of operation.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. As discussed above, the methods comprise administering compositions comprising distinct classes of agents.

Because different searches are required for each of the classes of agents, it follows that different searches are required for the methods employing the different classes of agents. Searching each of the distinct inventions would present a substantial burden to the Office.

6. Invention pairs I and V, II and VI, III and VII, and, IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the instant process can be practiced with materially different products. For instance, asthma is treated with albuterol and cancer is treated with taxol, which are distinct products from the instantly claimed combination compositions.

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. Because materially different products can be used in the instantly claimed method, the search of the instantly claimed method would not lead immediately to information about the instantly claimed products. Thus, different searches are required for the different inventions and restriction is proper.

8. This application contains claims directed to the following patentably distinct species: the species of non-glucocorticoid steroids; the species of tyrosine kinase inhibitors; the species of delta opioid receptor antagonists; the species of neurokinin receptor antagonists; the species of VCAM inhibitors; the species of ubiquinones; the species of diseases to be treated. The species of non-glucocorticoid steroids, tyrosine kinase inhibitors, delta opioid receptor antagonists, neurokinin receptor antagonists, VCAM inhibitors, and ubiquinones are independent or distinct because they are different chemical compounds with different structures, chemical and physical properties, bioavailabilities, pharmacokinetic profiles, and pharmacological efficacy. Because the species have different structures and properties, different searches are required for each species, which presents a substantial burden to the Office. The species of diseases to be treated are independent or distinct because they are different disorders with different pathophysiologies, etiologies, and art-recognized methods of treatment. For instance, as stated above, albuterol is known for the treatment of asthma and taxol for the treatment of cancer. However, albuterol is not used for the treatment of cancer and taxol is not used for the treatment of asthma. Thus, methods of treating the various diseases do not stem from the same inventive concept and they are distinct. Further, because methods of treating the different diseases are distinct, different searches are required for art and fulfilling the enablement requirements, which presents a substantial burden to the Office.

Note for clarity: Applicant is required to elect a single non-glucocorticoid steroid, a single antihistamine, a single ubiquinone, and a single disease (disease election is only for Group II) in order to comply with the election of species of requirement

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Because the restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See MPEP § 812.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

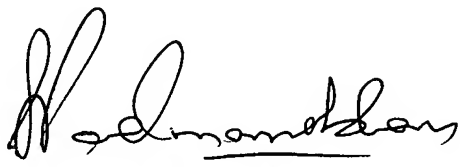
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin Capps whose telephone number is (571) 272-8646. The examiner can normally be reached on Monday-Friday, 7:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER